

# **ACNE SOLUTIONS SPOT HEALING ACNE MEDICATION- salicylic acid gel**

## **CLINIQUE LABORATORIES LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **ACNE SOLUTIONS SPOT HEALING ACNE MEDICATION**

#### ***Drug Facts***

#### **Active ingredient**

Salicylic Acid 1%

#### **Purpose**

Acne Treatment

#### **Uses**

- treats acne
- clears acne blemishes
- helps prevent development of new acne blemishes

#### **Warnings**

##### **For external use only**

**When using this product** using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

##### **Keep out of reach of children.**

If product is swallowed, call a doctor or contact a Poison Control Center right away.

#### **Directions**

- apply a thin layer to entire face twice a day after cleansing
- avoid eye area
- spot-apply if you are using another leave-on acne treatment
- if bothersome dryness or peeling occurs, reduce usage to every other day

#### **Inactive ingredients**

alcohol denat. • water/aqua/eau • acrylates/c10-30 alkyl acrylate crosspolymer • hamamelis virginiana (witch hazel) • laminaria saccharina extract • sea whip extract • butylene

glycol•benzalkonium chloride [iln32301]

**Other information**

protect the product in this container from excessive heat and direct sun

**PRINCIPAL DISPLAY PANEL - 15 ml Tube Carton**

acne

CLINIQUE

acne solutions

clinical

clearing gel

SALICYLIC ACID

ACNE MEDICATION

ALL SKIN TYPES

.5 FL.OZ.LIQ./15 ml e



## ACNE SOLUTIONS SPOT HEALING ACNE MEDICATION

salicylic acid gel

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:49527-825

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength      |
|---|-------------------|---------------|
| <b>SALICYLIC ACID</b> (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ) | SALICYLIC ACID    | 10 mg in 1 mL |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| <b>ALCOHOL</b> (UNII: 3K9958V90M)  |          |
| <b>WATER</b> (UNII: 059QF0KO0R)  |          |
| <b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO) |          |
| <b>WITCH HAZEL</b> (UNII: 101I4J0U34)  |          |
| <b>SACCHARINA LATISSIMA</b> (UNII: 68CMP2MB55)                                     |          |
| <b>PSEUDOPTEROGORGIA ELISABETHAE</b> (UNII: UDY3H1OUX5)                            |          |
| <b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)  |          |
| <b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)                                    |          |

**Packaging**

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49527-825-01 | 1 in 1 CARTON                                      | 04/06/2021           |                    |
| 1 |                  | 15 mL in 1 TUBE; Type 0: Not a Combination Product |                      |                    |

**Marketing Information**

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part333D                                 | 12/01/2008           |                    |

**Labeler** - CLINIQUE LABORATORIES LLC (044475127)**Registrant** - Estee Lauder Companies Inc. (790802086)**Establishment**

| Name                       | Address | ID/FEI    | Business Operations    |
|----------------------------|---------|-----------|------------------------|
| WHITMAN LABORATORIES, LTD. |         | 216866277 | MANUFACTURE(49527-825) |

**Establishment**

| Name                      | Address | ID/FEI    | Business Operations                    |
|---------------------------|---------|-----------|--|
| ESTEE LAUDER COMPANY, THE |         | 828534516 | REPACK(49527-825) , RELABEL(49527-825) |

| Establishment               |         |           |                        |
|-----------------------------|---------|-----------|------------------------|
| Name                        | Address | ID/FEI    | Business Operations    |
| ESTEE LAUDER COSMETICS, LTD |         | 244669714 | MANUFACTURE(49527-825) |

| Establishment               |         |           |   |
|-----------------------------|---------|-----------|---|
| Name                        | Address | ID/FEI    | Business Operations   |
| Estee Lauder Cosmetics Ltd. |         | 202952982 | MANUFACTURE(49527-825) , REPACK(49527-825) , RELABEL(49527-825) |

| Establishment    |         |           |                        |
|------------------|---------|-----------|------------------------|
| Name             | Address | ID/FEI    | Business Operations    |
| ESTEE LAUDER N.V |         | 370151326 | MANUFACTURE(49527-825) |

| Establishment                                 |         |           |   |
|---|---------|-----------|---|
| Name  | Address | ID/FEI    | Business Operations   |
| Len-Ron Manufacturing Division of Aramis Inc. |         | 809771152 | MANUFACTURE(49527-825) , REPACK(49527-825) , RELABEL(49527-825) |

| Establishment |         |           |  |
|---------------|---------|-----------|--|
| Name          | Address | ID/FEI    | Business Operations                    |
| NORTHTEC INC  |         | 943871157 | REPACK(49527-825) , RELABEL(49527-825) |

| Establishment |         |           |  |
|---------------|---------|-----------|--|
| Name          | Address | ID/FEI    | Business Operations                    |
| PADC 1        |         | 949264774 | REPACK(49527-825) , RELABEL(49527-825) |

| Establishment               |         |           |  |
|-----------------------------|---------|-----------|--|
| Name                        | Address | ID/FEI    | Business Operations                    |
| Estee Lauder Cosmetics Ltd. |         | 204132062 | RELABEL(49527-825) , REPACK(49527-825) |

Revised: 4/2021

CLINIQUE LABORATORIES LLC